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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,385

09/09/2004

Teizo Yoshimura

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EXAMINER

LEAVITT, MARIA GOMEZ

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/507,385	<b>Applicant(s)</b> YOSHIMURA, TEIZO	
	<b>Examiner</b> MARIA LEAVITT	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33 and 46-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 23-33 and 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Detailed Action***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Status of claims. Applicant's response to the Office Action of 12-28-2007 has been entered. Claims 1-33 and 46-54 are pending. Claims 33-45 have been canceled; claim 14 has been amended and claims 46-54 have been added by Applicants' amendment filed on 12-28-2007. Claims 1-10 and 23-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02-05-2007. Newly submitted claims 46-54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 46-54 are drawn to a method of activating a neutrophil or a lymphocyte and to a method of altering leukocyte migration, said inventions were restricted to Groups VI and VII, respectively, in the requirements for restriction/election filed on 01-03-2007. Accordingly, claims 46-54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.
3. Therefore, Claims 11-22 are currently under examination to which the following grounds of rejection are applicable.
4. The examiner acknowledges receiving the following documents: a Declaration under 37 C.F.R. § 1.132 signed by Dr. Hidenobu Kamohara, filed on 09-28-2007 and a Declaration under 37 C.F.R. § 1.132 signed by Dr. Teizo Yoshimura, filed on 09-19-2007; a Declaration

For Patent Application signed by Hidenobu Kamohara filed on 09-28-2007, a consent of Assignee Under 37 C.F.R. 1.497 regarding Inventorship consenting the addition of Dr. Hidenobu Kamohara as an inventor of the application and an unexecuted statement by Dr. Hidenobu Kamohara under CFR 1.497 filed on September 19, 2007.

### **Priority**

The instant application is the § 371 U.S. National Stage of International Application No. PCT/US02/39793, filed December 11, 2002, which was published in English under PCT Article 21 (2), which in turn claims the benefit of U.S. Provisional Application No. 60/363,734, filed March 12, 2002, U.S. Provisional Application No. 60/380,978, filed May 15, 2002, and U.S. Provisional Application No. 60/419,179, filed October 16, 2002. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original non provisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The disclosure of the prior-filed applications, U.S. Provisional Application No. 60/363,734, 03/12/2002; U.S. Provisional Application No. 60/380,978, 03/15/ 2002, and U.S. Provisional Application No. 60/419,179, 10/16/2002 provides adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application as follows: Claims 11-16 and 21-22 find support for the limitation “granulocyte-macrophage-colony stimulating factor” as recited in claim 13 in U.S. Provisional Application No. 60/363,734, 03/12/2002.

Claims 17-20 find support for the limitations “DDR1-activating antibody” as recited in claim 17 and the limitation “CD40 ligand” as recited in claim 20 in U.S. Provisional Application No. 60/419,179, 10/16/2002. Therefore, the effective filing date of 03/12/2002 is used for rejection of claims 11-16 and 21-22 and the effective filing date of 10/16/2002 is used for rejection of claims 17-20.

***Response to arguments***

***Action-Statement under 37 C.F.R. 1.497 Regarding Inventorship signed by Dr. Kamohara.***

Applicants are trying to add a new inventor, i.e., Dr. Hidenobu Kamohara, that was not originally in the in the international application after entering the national stage under 35 U.S.C. 371. The MPEP under § 1.41 (4) recites,

The inventorship of an international application entering the national stage under 35 U.S.C. 371 is that inventorship set forth in the international application, which includes any change effected under PCT Rule 92bis. See § 1.497(d) and (f) for filing an oath or declaration naming an inventive entity different from the inventive entity named in the international application, or if a change to the inventive entity has been effected under PCT Rule 92bis subsequent to the execution of any declaration filed under PCT Rule 4.17(iv) (§ 1.48(f)(1) does not apply to an international application entering the national stage under 35 U.S.C. 371).

However, the petition to change inventorship under 37 CFR 1.497 is defective for the following reasons: there is no indication that the International Bureau [IB] issued a form PCT/IB/306 noting that such a change was made. The lack of PCT/IB/306 form indicates that Dr. Hidenobu Kamohara was to be added as an inventor after PCT/IB/306 entered the national stage as Application 10/507,385 in the US. If Dr. Hidenobu Kamohara has been

added as an inventor under PCT Rule 92*bis* during the international phase, the IB would have issued a form PCT/IB/306 indicating this and during the national stage entry process in the US they could have come in with a declaration naming the old and the new inventors. But this isn't what happened. The original oath/declaration was one executed by the original sole inventor at the time the PCT application was filed, i.e., Dr. Teizo Yoshimura. This declaration was transmitted to the USPTO by the International Bureau and was sufficient under 37 CFR 1.497 to allow them to complete the National Phase oath/declaration entry requirements under 35 U.S.C. 371(c)(4) and 37 CFR 1.497. The USPTO issued a 903 Notification of Acceptance Under 35 U.S.C. 371 and 37 CFR 1.495 and a Filing Receipt. Hence there was only one inventor/applicant for the US and he was Dr. Teizo Yoshimura who signed the declaration. After the USPTO has properly issued the 903 and Filing Receipt, the applicant have now attempted to change the inventorship by adding an additional inventor Dr. Hidenobu Kamohara and Applicants have submitted the paperwork under 37 CFR 1.497 (d). However, 37 CFR 1.497(d) covers the situation where Applicants file a PCT application with one inventive entity and *before* they enter national in the US [or *before* they give the USPTO an acceptable oath/declaration in that national phase entry process] they have to change the inventive entity. This is not the case in the instant Application and a different legal process is required. This appears to be a Rule 48(a) situation where the applicant has presented a proper oath/declaration and now they want to change the inventorship. It is suggested that applicants should file a petition under 37 CFR 1.48(a) to change the inventorship. Finally, please note that for any future filings, all statements submitted as part of any petition to change inventorship must be properly executed.

***Notice of Non-Compliant Amendment- statement under 37 C.F.R 1.4***

On page 7 of Remarks, Applicants argue that the pending Notice of Non-Compliant Amendment indicates that the amendment submitted on September 19, 2007 is also considered non-compliant because "5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4): see attachment". Moreover, Applicants assert that "Applicants respectfully disagree with this rejection and note that the September 19, 2007 amendment, submitted via the Electronic Filing System (EFS), was signed using Applicants' representative's S-signature inserted between forward slash marks and included Applicants' representative's registration number immediately below the S-signature, fully in accordance with 37 CFR 1.4". Such is not persuasive.

The statement under 37 C.F.R 1.497 regarding inventorship filed electronically Via EFS on September 19, 2007, stating the clause " I, Hidenobu Kamohara, M.D., Ph.D., state that there was no deceptive intent on my part in the error of omitting my name as an inventor in PCT Application PCT/US02/39793 or U.S. National Stage Patent Application No. 10/507,385" has not been executed by Dr. Hidenobu Kamohara (see attached appendix).

***Withdrawn Rejections/Objections in response to Applicant arguments or amendments***

In view of Applicants' amendment of the specification at page 28, line 21, to correct the spelling of the word "sequence", objection to the specification has been withdrawn.

***Rejections/Objections maintained in response to Applicant arguments or amendments***

***Claim Rejections - 35 USC § 102 (a)***

Claims 11-16 and 21-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kamohara et al., (FASEB J. 2001 Dec;15(14):2724-6. Epub 2001 Oct 15).

***Response to Applicants' Arguments as they apply to rejection of claims 11-16 and 21-22 under 35 USC § 102 (a)***

At page 9 of Remarks filed on 09-19-2007, Applicants argue that Applicants have submitted evidence “in the form of a Declaration under 37 C.F.R. § 1.132 to overcome Kamohara et al. 1 The Declaration states that co-authors T. Yoshimura and H. Kamohara are inventors of the subject matter claimed in the present application. The Declaration also states that the remaining co-authors, S. Yamashiro and C. Galligan, are not inventors of the present application. Thus, Kamohara et al. is a disclosure made by the applicants themselves”. As such applicants contend that Kamohara et al. is not available as prior art. Such is not persuasive.

As stated in the paragraph above, the statement under 37 C.F.R 1.497 regarding inventorship filed electronically on September 19, 2007, is defective because a new inventor cannot be added under this Rule for the reasons explained in the paragraph above. Additionally, the statement by the proposed new inventor under 37 C.F.R 1.497 was unexecuted. Therefore, Kamohara et al., remains prior art.

***Claim Rejections - 35 USC § 103***

Claims 11-19 and 20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kamohara et al., (FASEB J. 2001 October 15, pp. 2724-6. Epub), in view of Lipford et al., (US



Pub No. 2003/0148316, Date of Publication August 7, 2003). Kamohara et al., is considered proper prior art as the inventive entity of the Kamohara reference is different from that of the instant application. The only shared inventor between the two is Teizo Yoshimura.

***Response to Applicants' Arguments as they apply to rejection of claims 11-19 and 20 under 35 USC § 103***

At page 9 of Remarks filed on 09-19-2007, Applicants argue "As discussed above, Kamohara et al. is not available as prior art against the current application. The secondary reference, Lipford et al., does not teach all the limitations of the claims. Lipford et al. discloses that DDR1 is expressed in plasmacytoid dendritic cells and that DDR1 expression levels may be elevated when these cells are incubated". Additionally, Applicants content at page 10 that "Lipford et al. fails to specifically disclose the step of contacting the immature macrophage or the immature dendritic cell with an effective amount of a DDR1-activating agent in order to induce maturation of the immature macrophage or the immature dendritic cell that expresses DDR1. Thus, Lipford et al. alone does not anticipate or render obvious claims 11-19 and 20". Such is not persuasive.

As stated in the paragraph above, the statement under 37 C.F.R 1.497 regarding inventorship filed electronically on September 19, 2007, is defective because a new inventor cannot be added under this Rule for the reasons explained in the paragraph above. Additionally, the statement under 37 C.F.R 1.497 was unexecuted by the proposed new inventor. Therefore, Kamohara et al., remains prior art. Moreover, as stated in the previous office action, Lipford et al., teaches the process of maturation of dendritic cells from PBMC by treatment with GM-CSF (p.1, [004]

[005]), said immature dendritic cells comprising cell surface markers including DDR1 that are upregulated after contact with a DDR1-activating agent, e.g., GM-CSF.

***Conclusion***

Claims 11-22 are not allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1633

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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